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Untreated Military Personnel Abusing Alcohol or Drugs

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14. ABSTRACT Year 1 focused on pre-trial activities including the development of the experimental and control substance abuse interventions, corresponding counselor manuals, research protocols, recruitment advertisements and recruitment plan. IRB approvals from the University of Washington and HRPO for both phase 1 (pre-trial) and phase 2 (randomized controlled trial) research activities were obtained.					
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INTRODUCTION:

This study will develop and test a brief telephone-delivered motivational enhancement intervention (MET) for substance abusing military personnel who are not currently in substance abuse treatment. The intervention is designed to prompt: (a) a willingness to participate voluntarily in a self-appraisal of substance abuse behavior and consequences, (b) self-initiated change or enrollment in a treatment or self-help program, and (c) cessation of abuse of alcohol or other drugs. Following focus groups with 30 participants, this study will recruit 240 military personnel who have a current substance use disorder via local publicity. The recruitment period will extend over a period of 36 months. Following screening and a baseline assessment, enrolled participants will be randomly assigned to one of two study conditions, each consisting of one 30-60 minute session by phone: (1) the experimental MET condition, or (2) a brief educational session. The MET session will involve a counselor using motivational interviewing strategies to establish an empathic relationship, to support the caller in candidly exploring the problems he/she has experienced with alcohol/drugs, and weigh the pros and cons of future options. The educational session will be didactic and provide information on alcohol and drugs. Participants in both conditions will be reassessed at three and six months following exposure to the intervention. Participation in the trial will be over the duration of 7 months for each participant.

BODY:

The aims of the study are to: (1) manualize participant recruitment mechanisms (e.g., newspaper and radio advertisements, public service announcements, news releases, culturally-specific publicity mechanisms for events, flyers and brochures to be disseminated to human services agencies); (2) develop a motivational enhancement intervention for delivery by telephone to military personnel who are engaging in substance abuse and are not in treatment; (3) evaluate its efficacy in promoting treatment seeking and engagement, and (4) assess its impact on alcohol and drug use outcomes. This yearly report covers the first year of the study (9/1/09-8/31/10) which focused on aims 1 and 2. The efficacy trial will begin in Year 2 and continue through Year 4.

Study Team Formation: Year 1 included the initial steps of hiring and forming a collaborative study team. A system for meeting with study investigators on 3 occasions per month was established. Project goals and goals specific to Year 1 activities were outlined and progressively worked toward throughout the year. Roles and responsibilities of team members were established. Relationships were formed with our collaborators at Joint Base Lewis-McChord and meetings were held monthly. Collaborators at Joint Base Lewis-McChord actively advise and educate our team regarding services available to army personnel, the cultural competence of our study materials, recruitment processes, and assist with recruitment of focus group participants and obtaining meetings with key figures on post. A Project Coordinator was hired and trained. In August of 2010, our counselors and research assistants were hired and training has begun accordingly.

Human Subjects Protection Review: The study team submitted human subjects protection applications for two phases of the research: pre-trial activities that included procedures for recruiting and conducting focus groups, and all activities associated with

the controlled trial. Human subjects protection reviews were conducted by the University of Washington (UW) Institutional Review Board (IRB) and the U.S. Army Human Research Protection Office (HRPO). IRB and HRPO approvals were obtained prior to the initiation of pre-trial activities. Now, as the date approaches for beginning the controlled trial, an application was submitted to the UW IRB and approved on June 11, 2010. The approved application was then submitted to HRPO. Minor modifications were requested by HRPO and those were addressed and submitted to the UW IRB and HRPO and approved by UW and HRPO on September 15, 2010 and September 17, 2010, respectively. An application for a Certificate of Confidentiality (for the controlled trial) was submitted to the National Institute on Drug Abuse and approved on August 21, 2010. All investigators completed the required Collaborative Institutional Training Initiative IRB training course.

Manualize Participant Recruitment Mechanisms: Print advertisements for the study have been developed. These include advertisements to be placed in newspapers, pamphlets to be included in orientation packets for troops returning from deployment and for soldiers who are new to Joint Base Lewis-McChord, banners and posters to be placed on post, flyers for distribution to post locations (such as service agencies, commissary, post exchange, health clinics, movie theaters, barracks, etc.), and advertisements on media screens throughout post. We have also collaborated with the Army Substance Abuse Program's prevention services to have our publicity materials included and introduced in alcohol and drug education classes. Several discussions with our colleagues at Joint Base Lewis-McChord have generated numerous employable ideas for recruitment with regard to on post advertisement placement.

Focus Groups: Separate focus groups were conducted with 10 military personnel who use substances, 7 military personnel who have completed or are currently engaged in substance abuse treatment, and 9 Joint Base Lewis-McChord service providers. Focus group participants were recruited to provide feedback on recruitment advertisements and intervention materials and provided ideas for advertisement placement. Findings from the focus groups were analyzed and used to edit the recruitment materials.

Develop and Manualize MET Intervention for Target Population: Counseling protocols were drafted for the MET and Education conditions. A personalized feedback report tailored to military personnel was developed. Feedback on the personalized feedback report was received and incorporated from the focus groups (described above) and our colleagues at Joint Base Lewis-McChord. Manuals for the Education and MET interventions have been developed as well. A counselor training protocol has been created. Counselors were hired and began training in August of 2010.

Conduct a Randomized Clinical Trial: Protocols for screening and assessment have been developed. Research assessment staff were hired and training began in August 2010. A web expert has been hired to create an on-line version of the follow-up assessment for participants who are unable to be reached by telephone for follow-up interviews. A webpage is under construction that will provide prospective participants information regarding the study. Recruitment for the main trial is anticipated to begin in early October 2010.

KEY RESEARCH ACCOMPLISHMENTS:

- Pre-trial activities approved by UW and HRPO IRBs
- Focus groups completed
- Recruitment advertisements developed
- MET intervention developed
- Education intervention developed
- Main trial activities approved by UW and HRPO IRBs
- Certificate of Confidentiality obtained for main trial

REPORTABLE OUTCOMES: N/A

CONCLUSION: The past year's activities have focused on the pre-trial development of recruitment and intervention materials needed to conduct the randomized clinical trial and the establishment of relationships at Joint Base Lewis-McChord that will facilitate a successful study. The accomplishments of this year perfectly position us for beginning the main trial on target.

REFERENCES: N/A**APPENDICES: N/A****SUPPORTING DATA: N/A**